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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,139	03/15/2004	Paul Haefner	GUID.609PA	9243
51294	7590	09/12/2005		
CRAWFORD MAUNU PLLC 1270 NORTHLAND DRIVE SUITE 390 ST. PAUL, MN 55120			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,139	HAEFNER, PAUL	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03152004;08152005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 6/1/2004 and 2/23/2004 are noted. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

2. The abstract of the disclosure is objected to because the length exceeds 150 words. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claim 27 is objected to because of the following informalities: "to" is missing between "coupled" and "the". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 11, 16, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 7 and 11, "a lead" is inferentially included. Because this element is not positively recited, it is unclear whether this element is part of the claimed invention. In regards to claim 16, the

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claim is vague because it fails to further limit the parent claim because the "patient-external device" has not been positively recited. It is suggested that applicant first claims the device before it is used. In regards to claims 22-24, the claims are hybrid claims because they recite method steps in apparatus claims, rendering the claims vague because it is unclear whether an apparatus or method is being claimed. Furthermore, it is unclear which element is performing the function of forcing the signals to be telemetered.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaldach (4,867,163).

8. In regards to claims 1, 32 and 44, Schaldach discloses an implantable housing (160) containing a plurality of electrodes (col. 8, lines 1 and 25), detection circuitry (111), a sensor to detect movement of the heart and produce an audio signal (117-120 and col. 7, line 61), a memory (112) to store the signals, a controller (113), and communications circuitry to telemeter the electrical and audio signals (125) to an external device (150).

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9. In regards to claims 2 and 35, Schaldach discloses a device using an accelerometer (col. 20, line 31 and claim 10). Please note that the "characteristic field" signal comprises the acceleration signal.
10. In regards to claims 3, 5 and 37, the sensor comprises a pressure transducer or a microphone (col. 20, line 67).
11. In regards to claims 6 and 10, the sensor and/or electrode is located on the housing (col. 9, line 21).
12. In regards to claim 7, the sensor is located on a lead (col. 9, line 20).
13. In regards to claims 9 and 39, at least one of the electrodes is configured for intrathoracic placement (col. 8, line 25).
14. In regards to claims 12 and 13, the device further comprises energy delivery circuitry, specifically pacing therapy (col. 7, line 13).
15. In regards to claims 16 and 25, the patient external device comprises a storage media to store the signals (159 and 153).
16. In regards to claims 30 and 38, the two signals are time correlated and is indicated by their concurrent display on the monitor (col. 23, line 46).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 17, 19-21, 41, 45 and 46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schaldach. Schaldach discloses that the user interface (150) provides a visual graphical output representative of the cardiac electrical signal (col. 23, line 20) and an audio output representative of the audio signal. Please note that the examiner is interpreting any manifestation of an audio signal as an audio output. Thus, although the output is displayed visually, it is still an audio output. In the alternative, it is well known in the art to provide audio signals representative of the audio events of the heart, for example by stethoscope or speaker, so that cardiac maladies can be quickly diagnosed by ear. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an audio output to Schaldach's invention to provide a means to quickly diagnose cardiac maladies by ear.

19. Claims 4 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Turcott (6,477,406). Schaldach discloses the essential features of the claimed invention except for a piezoelectric transducer. Turcott teaches of using a piezoelectric transducer with an implantable housing (col. 10, line 17) to provide an inexpensive mechanical-to-electrical transducer that is sensitive to a frequency band within the limits of human hearing and human heart sounds. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a piezoelectric transducer with an implantable housing to provide an inexpensive mechanical-to-electrical transducer that is sensitive to a frequency band within the limits of human hearing and human heart sounds.

20. Claims 8, 11, and 40 rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Kadhiresan (5,935,081). Schaldach discloses the essential features of the claimed invention except for subcutaneous, non-intrathoracic placement of the sensor/lead. Kadhiresan teaches of an implantable device with a heart motion detector, which is implanted subcutaneously and in a non-intrathoracic location (col. 2, line 59) to simplify the implantation and a lead to connect the electrodes to the housing (col. 3, line 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an implantable device with a heart motion detector, which is implanted subcutaneously and in a non-intrathoracic location to simplify the implantation and a lead to connect the electrodes to the housing.

21. Claims 14, 18, 22-24, 31, 33, 34, 43, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Gessman (5,321,618). Schaldach discloses the essential features of the claimed invention except for providing defibrillation therapy, providing an audio output for the cardiac electrical signal, providing a speaker, telemetering in response to a user request, telemetering in response to a patient-external device request, and telemetering in real-time. Gessman teaches of an implantable cardiac device that provides defibrillation therapy to treat a variety of arrhythmias, provides an audio output in the form of a speaker for outputting the cardiac electrical signal to transfer the signal information in a way that is perceivable to humans, telemetering in response to a user request and a patient external device request (col. 4, line 57) to allow transmission at a time that is convenient for the user, and telemetering in real-time to provide immediate information on the state of the

patient. Therefore, it would have been obvious to someone having ordinary skill in the art at the time the invention was made to modify Schaldach's invention by providing defibrillation therapy to treat a variety of arrhythmias, providing an audio output in the form of a speaker for outputting the cardiac electrical signal to transfer the signal information in a way that is perceivable to humans, telemetering in response to a user request and a patient external device request to allow transmission at a time that is convenient for the user, and telemetering in real-time to provide immediate information on the state of the patient. Please note that the examiner is interpreting the electromagnet device (26) as the patient external device that requests transmission. Since the patient applies this element to the proximity of the implant, it is also user-requested. Also, Gessman's teaching inherently transmits in real-time because the apparatus is lacking a memory (Fig. 1).

22. Claims 15, 26-29, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaldach in view of Riff et al. (2002/0026223 A1). Schaldach discloses the essential features of the claimed invention except for storing signals based on a patient-actuable trigger, a server coupled to the patient-implantable device and the patient external device, telemetering from the patient-implantable device to the server to the patient-external device, and telemetering from the patient-implantable device to the patient external device to the server. Riff et al. teach of an implantable device system which stores signals based on a patient-actuable trigger (par. 0026) to provide cardiac information whenever the patient desires, a server in communication with the implantable and external device (113) to store large amounts of patient data

that is accessible to many people, telemeters from the patient-implantable device to the server (102 to 112) to the patient-external device (112 to 118) to update the server and provide accurate server information to the external device, and telemeters from the patient-implantable device (102 to 104) to the patient external device to the server (104 to 112) to provide the patient with the data before it is sent to the server. Therefore, it would have been obvious to someone having ordinary skill in the art at the time the invention was made to provide Schaldach's invention with a system which stores signals based on a patient-actuatable trigger to provide cardiac information whenever the patient desires, a server in communication with the implantable and external device to store large amounts of patient data that is accessible to many people, telemeters from the patient-implantable device to the server to the patient-external device to update the server and provide accurate server information to the external device, and telemeters from the patient-implantable device to the patient external device to the server to provide the patient with the data before it is sent to the server.

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Additional examples of implantable devices with mechanical transduction are provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

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GEORGE R. EVANISKO
PRIMARY EXAMINER
6/29/5